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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/236,985	08/26/88	COOPER G	183/272

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EXAMINER	
LEE, L.	
ART UNIT	**PAPER NUMBER**
186	6

DATE MAILED: 07/19/89

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 1 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-45 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-45 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Ser. No. 236,985

Art Unit 186

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 186.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 5, 9, 19, 22 and 32-33, drawn to amylin or CGRP or derivatives thereof , classified in Class 530, subclass 307.

II. Claims 2-4, 6, and 23, drawn to compositions of insulin and amylin or CGRP, classified in Class 514, subclass 4

III. Claims 7-10, drawn to a method of treating diabetes mellitus, classified in Class 514, subclass 3

IV. Claims 11-18 and 20-21, drawn to preparations of amylin and derivatives of amylin classified in Class 514, subclass 3.

V Claims 29-31 and 34-35, drawn to method of preparation of amylin or amylin derivatives in crystalline form, classified in Class 514, subclass 3.

VI Claims 36-40, drawn to method for monitoring the therapy of diabetes mellitus or hypoglycemia, classified in Class 436, subclass 501.

VII Claims 43-47, drawn to a method of preparing amylin or derivatives thereof, classified in Class 530 subclass 307.

Claim 24-28 link(s) inventions I and II

Claim 41-44 link(s) inventions I and II.

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7/18/89

.The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product can be used in a process of treating hypotension.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability and (2) that the subcombination has utility by itself or in other combinations. (MPEP 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for patentability because the compositions of Group II can be used to monitor the treatment of hypoglycemia. The subcombination has separate utility such as in the treatment of hypotensin

Inventions I and IV are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a treatment for diabetes mellitus and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such

evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Inventions I and V are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a method of treating diabetes mellitus and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the compounds have utility in the treatment of hypotensin.

Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be

shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product can be prepared by solid phase.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter, and the search for group I is not required for groups II -VII, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is futher required under 35 U.S.C. 121 to elect a single disclosed species of amylin or CGRP derivative for whichever invention is elected. Examples of species are amylin, amylin-NH2, CGRP, specific peptide frament or specific conservative variant of amylin or CGRP.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

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An inquiry concerning this communication should be directed to Lester L. Lee at telephone number (703) 557-3770.

Lester L. Lee

LESTER L. LEE
PRIMARY PATENT EXAMINER
ART UNIT 186

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7/18/89